REMARKS

The abstract was objected to because the abstract on file is the full cover page of the PCT pamphlet. Accordingly, the abstract has been added by the above amendment on a new page at the end of the specification.

The Examiner has objected to the title as not descriptive, and has suggested a new title. The title has been amended in accordance with the Examiner's suggestion.

The drawings were objected to because two sets of drawings were filed on March 23, 2006, the set of drawings from the PCT pamphlet and a set of formal drawings of those filed with the priority provisional application. The latter differ from the PCT pamphlet drawings in that the empty boxes of the PCT drawings are filled in with the text shown in the priority application so as to be easier to understand. To resolve this dilemma, a new set of drawings labeled "Replacement Sheets" are enclosed which are the formal drawings of those filed with the priority provisional application.

Claims 1-8, 11, 16 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over US patent application publication 2002/0072671 (Chenal et al.)(now US Pat. 6,491,636) in view of US Pat. 6,443,896 (Detmer). Both references are commonly assigned to the assignee of the present application.

Amended Claim 1 describes a method for ultrasonically measuring the volume of a volumetric object of a body such as the heart in real time comprising repetitively acquiring ultrasonic images of the heart during a heart cycle in two intersecting image planes which extend through the heart in different directions at substantially the same time with an ultrasound probe; using an automated processor to define corresponding object borders in the ultrasonic images during the heart cycle; producing a plurality of quantified measures of the volume of the heart during the heart cycle from the defined object borders in the different directions; and displaying measures of the continuous change in the heart volume as the heart beats. An implementation of the invention of Claim 1 enables a sonographer with a 3D (volumetric) imaging probe to produce real time measurements of the changing volume of a heart chamber as the heart beats. The conventional way to measure the volume of the heart with a 3D probe is to acquire a static 3D image of the heart, then perform measurements of it by manual, automated or semi-automated means. But this will produce a volume measure at only one phase of the heart's cycle of expansion and contraction. The common solution to this is to make two measurements as Chenal et al. do, one at end diastole and another at end systole. The heart is thus measured at the two extremes of its range of motion.

A common way to measure the volume of the heart by 2D imaging is with the "rule of disks" (Simpson's rule), which analytically draws parallel lines across the 2D image of the heart chamber, then treats each line as the diameter of a disk of a predetermined height (the space between the parallel lines). The volume of each cylindrical disk is then calculated and summed to produce a measure of the heart volume. The fallacy in this technique, of course, is the assumption that the heart chamber is circular as the disks are, when in fact the heart is of an irregular shape. Consequently the rule of disks is accepted as only an approximate measure of the heart volume and is generally used comparatively rather than as an absolute measure.

The Detmer patent shows another imaging technique which can be performed with a 3D probe, which is to only scan a few (generally, two) image planes of a volume. This does not produce a true 3D volumetric image, of course, but only two image planes. The benefit is that the image planes can be rapidly scanned since the entire volume is not being scanned, and images of the scanned planes can be produced at a high real time frame rate, important when imaging a moving object such as the heart. But since only two planes are being imaged, the common wisdom is that this is insufficient for quantified measurements of the object. The Detmer patent is consistent with this thinking, as it is seen that it makes no suggestion of using the "biplane" technique for quantified measurements. When quantified measurements are to be done, the conventional wisdom is to use the probe in its full 3D mode and to perform the measurements on true 3D volumes as described above.

The present inventor has ignored this conventional thinking and surprisingly developed a technique which produces continuous quantified measures of the heart volume in real time. He uses the probe to acquire only a few image planes in real time and uses automated border detection to detect the heart borders in the images as they are produced. Since the image planes extend in different directions through the heart, their drawn borders measure at least two cross-sections of the heart as exemplified in Fig. 13a. This enables the inventor to use a modified form of the rule of disks. The analytical disks are not round, however, for the different directional measures provide at least two diameters for each disk. The disks may be approximately oval, for instance, with a long diameter and a short diameter. When the volumes of these disks are calculated and summed, a more precise measure of the heart volume is made as compared to the conventional rule of disks where the disks are assumed to be circular. Since only a few image planes are scanned the real time imaging rate is high, and the quantified measurements can likewise be made in real time to

give the sonographer a continuous, fairly accurate measure of the changing heart volume, as exemplified by the physiologic curve 218 of Fig. 12.

As mentioned in the previous response in this case, Chenal et al. do not produce measures of the volume of the heart in real time, nor do they produce real time measures of the changing heart volume during the heart cycle. They do automated border detection of images at the standard end diastole and end systole phases, and use the rule of disks as it is commonly used for 2D images to compute ejection fraction from these two phases (paragraph [0040]). Detmer describes the biplane technique which may be performed with a 3D imaging probe and recognizes its benefit of high frame rate, but, in accordance with the conventional thinking, makes no suggestion that biplane can be used for any measurements, let alone heart volume quantification. Consequently it is respectfully submitted that the invention of Claim 1, which enables the display of continuous measures of the changing heart volume in real time as the heart beat, is not an obvious combination of Chenal et al. and Detmer.

Amended Claim 11 describes a method for ultrasonically measuring the volume of a volumetric object of a body comprising acquiring a sequence of ultrasonic images of the heart in real time during a heart cycle in two intersecting image planes at substantially the same time with an ultrasound probe, the intersecting image planes extending in different directions through the heart volume; using an automated processor to define corresponding object borders in the ultrasonic images during the heart cycle; producing a real time graphical model of a volumetric region of the heart using the defined object borders; and producing from the defined object borders a real time measure of the changing heart volume during the heart cycle. An implementation of the method of Claim 11 can provide the same benefits as that of Claim 1, but further provides a real time graphical model of the volumetric region of the heart in addition to a real time changing volume measure, as exemplified in Figs. 12 and 13b. The sonographer can thereby observe the dynamics of the heart motion from the real time graphical model, and see the corresponding changes in the heart volume measure resulting from this motion. Since Chenal et al. do not produce measures of the volume of the heart in real time, nor do they produce real time measures of the changing heart volume during the heart cycle, and Detmer, while describing the biplane technique with a 3D imaging probe, makes no suggestion that biplane can be used for any measurements, let alone heart volume measurements, it is respectfully submitted that the combination of Chenal et al. and Detmer cannot render Claim 11 obvious.

Since Claims 2-8 depend from amended Claim 1 and Claims 16 and 17 depend from amended Claim 11, it is respectfully submitted that these claims are patentable over Chenal et al. and Detmer by reason of this dependency.

Claims 9, 10, and 12-15 were rejected under 35 U.S.C. § as unpatentable over Chenal et al. and Detmer and further in view of EP application 961135 (Mumm et al.) Mumm et al. was cited for its teaching of generating a 3D wireframe model of the heart using predefined contours to fit a surface to the model. Mumm et al. is like Chenal et al. in that it acquires its images at the outset, then performs its analysis in post-processing. Mumm et al. use a 2D probe which is incrementally moved to acquire cross-sectional images of a 3D volume. "Afterwards," these images are transformed into a 3D data set. Volumetric acquisition means "thereafter" creates a wireframe volume model. See paragraphs [0016], [0017], and [0022]. Mumm et al. can create several wireframe models of the same object in motion, then display them successively to represent a "moving" wireframe model (quotes used by the Mumm et al. inventors). This is not a real time graphical model as called for by Claim 11, but a moving model created by post processing well after the imaged motion has taken place. See paragraph [0019]. Thus, Mumm et al. fail to add anything to Chenal et al. and Detmer regarding real time measures of heart volume. Since Claims 9 and 10 depend from amended Claim 1 and Claims 12-15 depend from amended Claim 11, and Mumm et al. adds nothing to Chenal et al. and Detmer that would diminish the patentability of the independent claims over these citations, it is respectfully submitted that Claims 9, 10, and 12-15 are patentable over Chenal et al., Detmer and Mumm et al. by reason of their dependency.

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1-17 are patentable over Chenal et al. in combination with Detmer and Mumm et al. Accordingly it is respectfully requested that the rejection of Claims 1-17 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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